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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,183	01/03/2002	Harold Kleanthous	06132/037002	8491

21559 7590 06/14/2005

CLARK & ELBING LLP  
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BOSTON, MA 02110

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/039,183

Applicant(s)

KLEANTHOUS ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 1/3/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/02
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

5/02

### DETAILED ACTION

Claims 1-3,5-6 and 9 are pending.

#### *Information Disclosure Statement*

1. The information disclosure statement filed May 7, 2002 has been considered.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-3,5-6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection over the gene contained within the bacterial chromosome.

The claimed invention of claims a1-3, 5-6 and 9 are drawn to isolated polynucleotides that encode (comprises) any derivative or homolog that shares any number of amino acids of SEQ ID NO 2 or 4, or could be amplified with any of the recited sequences set forth in claims 5-6. The claims as written are being read as representative of a genus of genes that encode polypeptides, which need not evidence any specific biological function. The only coding sequence for a full length protein disclosed are SEQ ID NO 2 and 4. No other full length coding sequences for the protein of SEQ ID NO 2 or 4 are described. No allelic variants are described. No polynucleotide sequences are disclosed that have had insertions, deletions, or substitutions

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into any region of SEQ ID NO 2 or 4. No genes that only share 10, 20, 50, 75 or 100 amino acids with SEQ ID No 2 or 4 are described. The instant specification states that within the scope of the invention are variants (derivatives) of the disclosed SEQ ID NO. No specific variants of the coding region that reads on a gene are disclosed. No specific regions where variability in nucleotide sequence would be tolerated upon translation of the nucleotide sequence into a stable *Helicobacter* protein have been disclosed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only an isolated polynucleotide consisting of a nucleotide sequence encoding SEQ ID NO: 2 or 4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Example 7, found on the USPTO website.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims <sup>1-3,5,6</sup> 1-3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Burucoa et al (Nucleotide sequence and characterization of peb4A encoding an antigenic protein of Campylobacter jejuni, protein accession number Q46105, and nucleotide sequence X84703, created in EMBL February 17, 1995 and published in Res. Microbiology, Vol. 146(6), pages 467-476, 1995).

Burucoa et al disclose a isolated polynucleotide sequence that is homologous to the amino acid sequence of a Helicobacter polypeptide that comprises an amino acid sequence of SEQ ID NO 2 and was produced as a recombinant mature form of the protein, which is also a derivative of the polypeptide of SEQ ID NO 2 (see sequence alignment attached herewith), wherein the derivative and homologous polynucleotide is from Campylobacter jejuni which could be amplified with the recited primers which would hybridize to conserved sequences of Campylobacter jejuni coding sequence for peb4A.

Burucoa et al anticipates the instantly claimed isolated polynucleotide as now claimed.

3. Claims <sup>1-3,5,6</sup> 1-3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yura et al (Nucleotide sequence and characterization of sur4A encoding an antigenic protein of Escherichia coli, protein accession number

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P21202, and nucleotide sequence D10483, created in EMBL August 6, 1992 and published in Nucleic Acids Research , Vol. 20, pages 3305-3308, 1992) as evidenced by PG-pub 20040115767 [0073].

4. Yura et al (EMBL accession number D10483) disclose a isolated polynucleotide sequence that is homologous to the amino acid sequence of a Helicobacter polypeptide that comprises an amino acid sequence of SEQ ID NO 2, which is also a derivative of the polypeptide of SEQ ID NO 2, wherein the derivative and homologous polynucleotide encodes a SurA polypeptide from Escherichia coli.

5. Yura et al inherently anticipates the instantly claimed isolated polynucleotide as now claimed, as evidenced by PG-pub 20040115767 [0073] which provides that identifies the Helicobacter pylori protein known as HPO175, which is the instantly claimed SEQ ID NO 2, is homologous to Escherichia coli surA polypeptide.

6. Claims <sup>1-3, 5, 6</sup> and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ludwig et al (Nucleotide sequence and characterization of tuf gene encoding an antigenic protein of Wolinella succinogenes accession number P42482, and nucleotide sequence X76872, created in EMBL September 15, 1994 and published in Antonie Van Leeuwenhoek, Vol. 64(3-4) pages 285-305, 1993).

Ludwig et al disclose a isolated polynucleotide sequence that is homologous to the amino acid sequence of a Helicobacter polypeptide that comprises an amino acid sequence of SEQ ID NO 4, which is also a derivative of the polypeptide of SEQ ID NO 4 (see sequence alignment attached herewith), wherein the derivative and homologous polynucleotide is from Wolinella succinogenes, a member of the family of bacteria call Helicobacteraceae. Ludwig et al anticipates the instantly claimed isolated polynucleotide as now claimed.

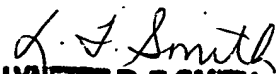
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***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tomb et al(1997) is cited to show SEQ ID NO 2 of the instant Application to have been referred to as HPO175. and cell binding factor 2 (see sequence alignment ).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
June 7, 2005

  
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